



United States
Department of
Agriculture

Food and
Nutrition
Service

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SUBJECT: WIC Final Policy Memorandum # 2005-1A
Implementation of Certain WIC Vendor Provisions of P.L. 108-265

TO: Regional Directors
Supplemental Food Programs
All Regions

This policy memorandum is an addendum to WIC Policy Memorandum # 2005-1, *Implementation of Certain WIC Vendor Provisions of P.L. 108-265*, which was issued on December 6, 2004. Several WIC State agencies have raised a number of questions that require clarification. Therefore, this policy memorandum provides clarification on: 1) notification of vendor violations; and, 2) the list of infant formula manufacturers, wholesalers, distributors, and retailers.

Notification of Vendor Violations

The following clarification pertains to the notification of vendors concerning violations requiring a pattern. Section 246.12(l)(1)(iii) of the WIC regulations requires the State agency to establish the patterns of violations (number of violative instances, and, in some cases, kinds of violative instances) which must be detected in an investigation in order to impose certain mandatory sanction on a vendor. Also, under § 246.12(l)(2), a State agency is permitted, although not required, to establish such patterns for State agency sanctions. As noted in WIC Policy Memorandum # 2005-1, Section 203(c)(5) of the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265, amends Section 17(f) of the Child Nutrition Act of 1966 (CNA) by adding a new paragraph (26) to require the State agency to notify the vendor of the initial violation, prior to documenting another violation, for violations requiring a pattern of occurrences in order to impose a sanction. The only exception is when the State agency determines that notifying the vendor would compromise an investigation.

Several State agencies have requested clarification on whether a State agency may sanction a vendor based on violations detected in the initial compliance buy visit if those violations fulfill the State agency's pattern requirement, even though a notice of violations has not been provided to the vendor. We have also been asked several related questions.

For investigations beginning on or after October 1, 2004, a pattern may not be established based solely on violations occurring during one compliance buy visit, even if violations on several food instruments occur during that one compliance buy visit. This is true regardless of whether the State agency determines that notifying the vendor would compromise the investigation. For example, if a State agency requires three violations as the pattern for overcharging, and the vendor initially commits this violation by overcharging on three food instruments during one compliance buy visit, the State agency may not sanction the vendor without two additional overcharging violations detected during one or more subsequent compliance buy visits.

The intent of the new law is that vendors be provided notification that violations had occurred prior to documenting another violation, unless such notification would compromise an investigation. As such, to allow a pattern to be identified during one compliance buy visit would be contrary to the intent of the law. If the State agency provides notification to the vendor it may cite all of the violations in the notification letter. However, the State agency must treat all of the violations from the first compliance buy visit as one occurrence in the pattern determination.

Also, if the vendor commits a different violation in a subsequent compliance buy visit, the State agency must provide the vendor with a notice specifying that violation before sanctioning the vendor based on such different violations. Further, we also encourage State agencies to attach a copy of the sanctions schedule to any notification of violations, to provide greater assurance that a vendor is on notice of all sanctionable violations prior to a subsequent compliance buy visit.

However, a State agency may determine that any notification on a different violation would compromise the investigation, even though the State agency had not determined that the first notice would compromise the investigation. The State agency may choose not to send a notification regarding the new or different violations identified in a subsequent compliance buy visit. The State agency must make determinations on a case-by-case basis and document the basis for its determination in the vendor's file.

The State agency may conduct another compliance buy visit at anytime after the notice of violation is received by the vendor. The State agency may use the same method of notification which the State agency uses to provide a vendor with adequate advance notice of the time and place of an administrative review per section 246.18(b)(3) of the WIC Regulations.

List of Infant Formula Wholesalers, Distributors, Retailers, and Manufacturers

Section 203(e)(8) of the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265, amends Section 17(h)(8)(A) of the CNA by requiring that each State agency: 1) maintain a list of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with the Food and Drug Administration (FDA) that provide infant formula; and, 2) require authorized vendors to only purchase infant formula from sources on the above-described list.

Some State agencies have asked if the State agency has discretion to restrict the authorized list, e.g., to wholesalers designated in an infant formula rebate contract or only to distributors that purchase directly from the manufacturer. While Section 203(e)(8) prohibits authorized vendors from purchasing infant formula from sellers not on the State's list of licensed wholesalers, distributors, retailers and registered manufacturers, it does not address the question whether a State could further restrict the sources of infant formula available to authorized vendors. However, neither section 203(e)(8) nor the WIC regulations provide an independent basis for excluding licensed suppliers. Thus, any restrictions regarding this list must be established in accordance with State/ITO law and/or regulations. State agencies should consult with their legal counsel to determine the correct process for implementing any

restrictions on the list of infant formula wholesalers, distributors, and retailers licensed in accordance with State/ITO law and/or regulations.

Also, a State agency has asked whether tax registration would be considered a State/ITO “license” within the meaning of the statutory provision. In fashioning this statutory provision, Congress recognized that “licensing requirements and types may vary significantly among States,” noting, for example, that some States may have health licensing requirements while other States have business licensing requirements. (House Committee on Education and the Workforce, Report No. 108-445, 3/23/04, pp. 59-60) If no other form of licensing applies to infant formula suppliers within a State/ITO, such tax registration would constitute such licensing for the purposes of the above-noted statutory provision. Congress certainly did not intend that any State/ITO would be unable to include wholesalers, distributors, or retailers on its list because of the kind of State/ITO laws and regulations governing health and business matters. Thus, assuming that a State/ITO has no other kind of health or business licensing, then tax registration would suffice.

Finally, attached is a list of the infant formula manufacturers registered with the FDA. FNS has obtained the names of these registered manufacturers from the FDA. Some State agencies have also requested a list of infant formula distributors which are registered with the FDA. However, as noted above, the law requires that State agencies provide their WIC-authorized vendors with a list of infant formula distributors licensed under State law, not registered with the FDA.

/s/

PATRICIA N. DANIELS

Director

Supplemental Food Programs Division

Attachment

Infant formula manufacturers that are currently (updated 2/18/05) registered with the FDA and are marketing infant formulas in the U.S.:

1. Bristol-Myers Squibb Company

Bristol-Myers Squibb Company
Mead Johnson Nutritional Group
2400 West Lloyd Expressway
Evansville, IN 47721-0001

2. Nestle, USA

Nestle USA
800 North Brand Blvd.
Glendale, CA 91203

3. Ross Products

Ross Products Division
Abbott Laboratories
625 Cleveland Avenue
Columbus, Ohio 43215-1724

4. SHS North America

SHS North America
9900 Belward Campus Drive, Ste. 100
Rockville, MD 20850

5. PBM Nutritionals

PBM Nutritionals, LLC
P.O. Box 2109
147 Industrial Park Road
Georgia, Vermont 05468-2109

6. Solus Products, LLC

Solus Products, LLC
8910 Purdue Road, Suite 230
Indianapolis, IN 46268